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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KIERAN P.J. MURPHY

Appeal 2008-1756
Application 09/594,685
Technology Center 3700

Decided: May 21, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-23. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to a tray comprising vertebroplasty components. Vertebroplasty is a surgical procedure in which a biomaterial is injected into a vertebral body of the spine to strengthen it (Spec. 1-2).

Claims 1-23 are pending (App. Br. 3). Appellant appeals the following rejections:

1) Claims 17-19 as anticipated under 35 U.S.C. § 102(b) by Lazarus (U.S. Pat. No. 4,128,173, Dec. 5, 1978) (Ans. 5);

2) Claims 1-16, 20, and 21 as obvious under 35 U.S.C. § 103(a) over Vagley (U.S. Pat. No. 6,158,437, Dec. 12, 2000) (Ans. 5);

3) Claims 1-16, 20, and 21 as obvious under 35 U.S.C. § 103(a) over Vagley, Shanley (U.S. Pat. No. 5,626,230, May 6, 1997), MacLeod (U.S. Pat. No. 5,506,257, Apr. 9, 1996), Smith (U.S. Pat. No. 5,690,618, Nov. 25, 1997), Arlers (U.S. Pat. No. 3,910,273, Oct. 7, 1975), Racz (U.S. Pat. No. 5,817,074, Oct. 6, 1998), Jiang (U.S. Pat. No. 5,847,046, Dec. 8, 1998), Singer (U.S. Pat. No. 5,147,308, Sep. 15, 1993), Draenert (U.S. Pat. No. 5,645,347, Jul. 8, 1997), Haynie (U.S. Pat. No. 5,240,415, Aug. 31, 1993), Hertzmann (U.S. Pat. No. 5,084,043, Jan. 28, 1992), and Baker (U.S. Pat. No. 4,554,686, Nov. 26, 1985) (Ans. 6); and

4) Claims 22 and 23 as indefinite under 35 U.S.C. § 112, second paragraph (Ans. 4)

We select claims 1, 17, and 22 as representative of the appealed subject matter. Claims 1, 17, and 22 read as follows:

> 1. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:
>
> a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;
>
> a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;
>
> a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

17. A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

22. The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;
a local anaesthesia aspiration syringe;
a local anaesthesia aspiration needle;
a local anaesthesia injection needle;
a liquid monomer;
a monomer aspiration needle;
a monomer aspiration syringe;
a mixing bowl;
a mixing spatula;
a polymer powder;
an opacifier;
a scalpel; and
a vertebroplasty needle.

ANTICIPATION OVER LAZARUS

Claims 17-19 stand rejected as anticipated under 35 U.S.C. § 102(b) by Lazarus.

Issue

The Examiner finds that Lazarus discloses a kit which comprises first and second trays, individually assembled and packaged (Ans. 5). The Examiner states that the Lazarus's tray 10b includes a syringe and needle and that tray 10a includes a cannula for injecting or aspirating fluid, each of which are capable of being used in a spinal surgical procedure (Ans. 8) and therefore which meet the limitations of claim 17 of "vertebroplasty injection components."

Appellant contends that the phrase "vertebroplasty injection components" as recited in claim 17 requires the kit to comprise needles which are "sufficiently robust for injection of bone cement" in a vertebral body (App. Br. 16).

Thus, the issues to be considered in this rejection are as follows: 1) whether the claimed "vertebroplasty injection components" requires components which must be capable of injecting a biomaterial ("bone cement") into the pedicle of a vertebral body; and 2) if so, whether the components in the Lazarus kit are capable of meeting this limitation.

Claim interpretation

The first issue is one of claim interpretation. Thus, we turn to the language of claim 17.

Claim 17 is directed to a "vertebroplasty kit" for performing vertebroplasty. Vertebroplasty is surgical procedure in which a biomaterial is injected into a vertebra to strengthen it (Spec. 1-2). The kit comprises "first" and "second" trays of "vertebroplasty injection components for performing a . . . vertebroplasty injection through a [first and second, respectively] pedicle of the vertebral body." The second tray of components

"can remain sterile for use in another vertebral body if" the first injection, using the components of the first tray, is sufficient to strengthen the vertebral body.

Each tray comprises "vertebroplasty injection components" which are "for performing a vertebroplasty injection through a . . . pedicle of a vertebral body." These terms indicate an intended use of the claimed components which do not necessarily limit their structure. However, in this case, we find that the phrase "vertebroplasty injection components" is also a description of the component structure. According to the Specification, vertebroplasty injection involves inserting a "vertebroplasty needle" into a vertebral pedicle and body (Spec. 9: 26-28). Once inserted into the desired location, a bone cement material is injected through the needle into the vertebral body (Spec. 10: 6-8) to strengthen it. The needles utilized to inject the material are described as preferably 11 and 13 gauge (Spec. 6: 2-6). Thus, we interpret "vertebroplasty injection components" to include components which have a structure enabling them to be utilized to inject a bone cement,[1] e.g., an 11 or 13 gauge needle (to pierce the pedicle), as well as a syringe or other means to hold the cement for injection through the vertebroplasty needle.

[1] We have focused here on the vertebral body injection function of the claimed "vertebroplasty injection components" because this function is in dispute in the rejection. However, we note that claim 22, which depends on claim 17, comprises "vertebroplasty injection components" in which this function is not necessary, such as "local anaesthesia."

The Lazarus patent

1. Lazarus describes a package 10, for peritoneal cavity treatment (Lazarus, at col. 1, ll. 9-13), comprising two halves, 10a and 10b, "each separately sealed and openable" (*id*. at col. 7, ll. 41-42; Fig. 1).

2. First half 10a is shown as having a catheter 12 and cannula 16; the second half 10b is shown as having a syringe 36 and needle 38 (Lazarus, at col. 7, ll. 36-41; Ans. 8).

3. Cannula 16 is sized in length and diameter for inserting into the peritoneal cavity (Lazarus, at col. 5, l. 67 to col. 6, l. 21).

4. The needle 38 is for injecting a local anesthetic into the skin and is 26 gauge (Lazarus, at col. 3, ll. 35-39).

Analysis

We have interpreted each tray of the kit of claim 17 to require components, such as an injection needle or a syringe, which are capable of injecting a bone cement through a pedicle of a vertebral body. The Examiner finds that

> Lazarus's tray 10b includes a syringe 36 and needle 38 and they are capable of being used in a spinal surgical procedure, e.g. for injecting anesthesia. Lazarus's tray 10a includes a cannula for injecting and/or aspirating fluid and it is capable of being used in a spinal surgical procedure, e.g. for injecting or aspirating nucleus pulpous [sic, pulposus[2]].

(Ans. 8). The Examiner concludes that Lazarus meets all the limitations of claim 17, and thus anticipates the claim, because "each tray includes an

[2] The nucleus pulposus is "central portion of intervertebral disks, consisting of a pulpy elastic substance" (Murphy Dec. ¶ 9)

injection component [that] . . . can perform a function in spinal surgery if one so desire[s]" (*id.*).

The PTO does not have the ability "to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Thus, once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). In this case, because halves 10a and 10b (FF 1) contain components that could be utilized for injection – the catheter and cannula in 10a (FF 2, 3) and the syringe and needle in 10b (FF 2, 4) – we find that the Examiner has "sound basis for believing that the products of the applicant and the prior art are the same," shifting the burden to Appellant to provide rebuttal arguments or evidence.

To rebut anticipation, the named inventor, Dr. Kieran P.J. Murphy, provided a declaration under 37 C.F.R. § 1.132 ("Murphy Dec."). Dr. Murphy states that needle 38 in 10b of Lazarus is "thin-walled and not suitable for vertebroplasty injection" (Murphy Dec. ¶ 8). Dr. Murphy explains that a "bone-cement injection needle suitable for vertebroplasty injection is much more robust (typically eleven gauge or thirteen gauge, see my Application at page 6, lines 3-6, although sometimes a 14 gauge needle would be used) than the needles described by Lazarus (26 gauge, see Lazarus at column 1, lines 37-39)" (*id.*).

With regard to the cannula 16 in 10a of Lazarus, Dr. Murphy states that it "would be too small for injecting or aspirating nucleus pulposus (the central portion of intervertebral disks, consisting of a pulpy elastic

substance" (Murphy Dec. ¶ 9). The inventor also states that "injecting or aspirating nucleus pulposus . . . is not vertebroplasty injection (*id.*)

"[P]atentability is determined on the totality of the record, by a preponderance of the evidence." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). In this case, we find that the Examiner has met the burden of establishing prima facie anticipation and that Appellant has not provided adequate evidence to rebut it.

In determining that Lazarus anticipates claim 17, the Examiner made the finding that 10b of the Lazarus package contains a syringe 36 and a syringe needle 38 which could be used in a spinal surgical procedure (Ans. 8). Dr. Murphy, the inventor, and also a surgeon who has performed over "500 vertebroplasty injection surgeries" (Murphy Dec. ¶ 1), declares that needle 38 is not "suitable for vertebroplasty injection" because it is thin-walled and has a smaller gauge (id. at ¶ 8; *see* also fn. 1).

The Examiner rejects this evidence because "the declaration is directed to an opinion from applicant and not to evidence" (Ans. 8). We do not agree. Dr. Murphy provides a factual basis for his opinion: Lazarus's syringe needle is described as 26 gauge (FF 4) which would make it thin-walled and insufficiently robust for injection into a pedicle in comparison to the lower gauge needles described in the Specification (Murphy Dec. ¶ 8). We agree that there is a conflict of interest, and hence potential bias, when an inventor provides a declaration distinguishing the claimed invention from the prior art; however, in this case, we can guard against it by scrutinizing the underlying factual basis for the opinion. Since we see no defect in the facts presented by Dr. Murphy, and the Examiner has failed to unveil any, we conclude that Appellant has rebutted the Examiner's assertion that needle

38 can be used for injection through a pedicle of a vertebral body as required by claim 17.

For the syringe 36, Dr. Murphy states that "[i]n my opinion, the syringe" is not a "vertebroplasty component[]" (Murphy Dec. ¶ 12; see also ¶ 7). In this case, Dr. Murphy does not identify a reason, or point to facts, as to why the syringe could not carry bone cement to be injected into a pedicle when attached to a vertebroplasty needle.[3] Thus, we do not find the declaration to be persuasive on this point – and conclude to the contrary – that syringe 36 is a vertebroplasty component as in claim 17.

Dr. Murphy also states that "Lazarus's preferred Becton-Dickinson 18G23/4 thin wall catheter cannula 16 [in half 10b of Lazarus] would be too small for injecting or aspirating nucleus pulposus" (Murphy Dec. ¶ 9). He asserts that "injecting or aspirating nucleus pulposus . . . is not vertebroplasty injection, and a cannula for injecting or aspirating nucleus pulposus is not a vertebroplasty injection component" (*id.*).

We are not persuaded by this evidence. The requirement in claim 17 that the "vertebroblasty injection components" are "for performing a vertebroplasty injection" imposes the structural requirement that the component be capable of piercing a pedicle. While the Lazarus cannula is for inserting into a peritoneal cavity (FF 1, 3), this does not preclude it from also being capable of injecting into a vertebral pedicle – thus meeting the limitation of claim 17. Dr. Murphy states that "cannula 16 is too small for

[3] Claim 22, which depends on claim 17, lists "a local anaesthesia aspiration syringe" and "a monomer aspiration syringe" as "vertebroplasty injection components." Thus, syringes appear to meet the claimed limitation of vertebroplasty injection components, even if not used to inject cement into the vertebral body.

injecting or aspirating nucleus pulposus," but he also states that "a cannula for injecting or aspirating nucleus pulposus is not a vertebroplasty injection component" (Murphy Dec. ¶ 9). Thus, there is no statement in the declaration that cannula 16 could not be used to inject through a pedicle as required by claim 17.

In sum, we conclude that Appellants have not provided sufficient evidence to rebut the Examiner's prima facie case. Thus, we affirm the rejection of claim 17 as anticipated by Lazarus. Claims 18 and 19 fall with claim 17 because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS OVER VAGLEY

Claims 1-16, 20, and 21 stand rejected under 35 U.S.C. § 103(a) over Vagley.

Claims 1-16, 20, and 21 stand rejected under 35 U.S.C. § 103(a) over Vagley, Shanley, MacLeod, Smith, Arlers, Racz, Jiang, Singer, Draenert, Haynie, Hertzman, and Baker.

Issue

We have selected claim 1 as representative of the appealed subject matter. *See* 37 C.F.R. § 41.37(c)(vii)(1). Claim 1 is directed to a tray of vertebroplasty components comprising: a local anesthesia assembly, a bone cement assembly, a surgical cutting instrument, and a device for injecting biomaterial into a vertebral body.

The Examiner finds that Vagley describes an instrument support tray having a plurality of surgical instruments (Ans. 5). The Examiner also finds that Vagley states that the "tray can be customized" for performing specific

surgical procedures (*id*.). Based on this suggestion, the Examiner contends that it would have been obvious to assemble in a single instrument tray all the components for vertebroplasty as recited in claim 1 (*id*. at 6). Additional references (Shanley, MacLeod, Smith, Arlers, Racz, Jiang, Singer, Draenert, Haynie, Hertzman, and Baker) are cited by the Examiner as evidence that vertebroplasty components were known in the art.

Appellant contends that Vagley does not teach or suggest the claimed combination of components recited in claim 1.

Thus, the issue in these rejections is whether Vagley's teaching would have suggested the claimed tray of known vertebroplasty components.

The Vagley patent

5. Vagley describes an instrument supporting tray which includes instruments in specific positions "to establish a sequence which corresponds generally to the sequence in which the surgical instruments will be employed" in a surgical procedure (Vagley, Abstract).

6. A "surgical procedure" is defined by Vagley as "procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive (Vagley, at col. 3, ll. 5-10; see Ans. 12).

7. Vagley provides a specific example of a tray of instruments for a rhinoplasty (Vagley, at col. 4, ll. 32-35).

8. Vagley states that the tray may be

> customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All of this is

> directed toward enhanced efficiency in the surgical suite and more accurate and prompt delivery of the correct instrument to the surgeon and return of the same to the tray after use.

(Vagley, at col. 5, ll. 43-50; *see* Ans. 11-12).

Analysis

In making an obviousness determination, the Examiner must first identify the scope and content of the prior art and then ascertain the differences between the prior art and the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Once the differences between the prior art and the claimed invention have been identified, the next step is to identify motivation or a reason why persons of ordinary skill in the art would have been prompted to combine the prior art to have made the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Vagley describes a kit comprising different components for performing surgery, but does not contain the specific components recited in claim 1. However, the Examiner finds that Vagley teaches that the "tray can be customized" for performing specific surgical procedures, providing a reason to have assembled the components recited in claim 1 into a single tray in order to perform vertebroplasty, which is a surgical procedure (Ans. 5). The Examiner also provides evidence that the surgical components for vertebroplasty were known in the art.

Appellant contends the "Examiner has used Applicant's claims as a shopping list to find patents that teach each *element*" of claim 1 (App. Br. 17). Appellant argues that the "Vagley patent discloses a tray and says things *other than* vertebroplasty components should be on the tray. So Vagley does not teach or suggest *Applicant's* combination, Vagley teaches a *different*

combination" (App. Br. 17). Dr. Murphy makes similar statements in his declaration (Murphy Dec. ¶ 14).

The Examiner has the better argument. As noted by the Examiner, Vagley is not limited to a rhinoplasty instrument tray (FF 5, 6, 8). Vagley explicitly states that the instrument tray may be "customized to cater to the preference of a specific surgeon during a specific procedure" (FF 8). Further, Vagley defines surgical procedures broadly to include "at least partially invasive" procedures performed by "physician, dentist, veterinarian or other legally authorized health care professional" (FF 6). Thus, the Examiner's finding that Vagley's teachings suggest utilizing the surgical tray for other surgical procedures, including vertebroplasty (Ans. 6-7, 11), is supported by the evidence of record.

We do not agree with Appellant that the Examiner has used claim 1 as "shopping list" (App. Br. 17). The Examiner relies on Vagley's teaching of an instrument tray containing a plurality of instruments used in a single surgical procedure as suggesting a tray of components for vertebroplasty, all of which were known in the art. Appellant does not rebut the Examiner's findings that the specific components recited in claim 1 are those used in a typical single vertebroplasty procedure; thus, there is no evidence that the Examiner has used claim 1 as shopping list. To the contrary, the Examiner's position – which is unrebutted – is that the components recited in claim 1 are those which would normally be used to perform vertebroplasty.

We also do not find Dr. Murphy's declaration persuasive. Dr. Murphy states:

> In my opinion, neither the Vagley Patent alone, nor the Vagley Patent in combination with the 11 other references upon which the Examiner relies, would suggest to a person of ordinary skill

> in the art, the combinations claimed in my Claims 1-16, 20 and 21.

(Murphy Dec. ¶ 14).

> While objective factual evidence going towards a §103 determination is preferable to statements of opinion on the issue, the nature of the matter sought to be established, as well as the strength of the opposing evidence, must be taken into consideration in assessing the probative value of expert opinion. *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978). Opinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. See FED.R. EVID, 701-704; *Orthopedic Equipment Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983). Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination. Cf. *In re Altenpohl*, 500 F.2d 1151, 1158 (CCPA 1974).

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 294 (Fed. Cir. 1985).

In this case, there are no factual underpinnings for Dr. Murphy's statement that "the Vagley Patent alone, nor the Vagley Patent in combination with the 11 other references" (Murphy Dec. ¶14) would not have suggested the subject matter of claim 1. In contrast, the Examiner has provided adequate evidence to support his position (i.e., the fact that vertebroplasty was a known procedure and the teaching that the components to accomplish the procedure were known in the art). Thus, when we consider the totality of evidence in the record before us, we conclude that the Examiner did not err in concluding that claim 1 would have been obvious over Vagley alone, or in combination with the cited prior art. We affirm the rejection of claim 1. Claims 2-16, 20, and 21 fall with claim 1 because

separate reasons for their patentability were not provided. *See* 37 C.F.R. 41.37(c)(1)(vii).

INDEFINITENESS

Claims 22 and 23 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. We have selected claim 22 as representative. Claim 22 depends on claim 17, and further requires that the vertebroplasty injection components of claim 17 comprise thirteen specifically recited components (i.e., local anaesthesia, local anaesthesia aspiration needle, etc.). The Examiner contends that the claim is indefinite because it is not clear whether all thirteen of the recited components are represented in each of the first and second trays, or whether a specific component in the list is either in the first or second tray, but not in both (Ans. 4).

Appellant contends that the claims are clear because there is antecedent basis for "the vertebroplasty injection components" in both lines 3 and 5 of claim 17 (App. Br. 14), for the first and second trays, respectively.

We agree with Appellant. Because there is antecedent basis in claim 17 for both a first and second tray of "vertebroplasty injection components", persons of skill in the art would understand that each tray comprises all of the components recited in claim 22.

We reverse the rejection of claims 22 and 23.

CONCLUSION

We affirm the prior art rejections of claims 1-21, but reverse the rejection of claims 22 and 23 under 35 U.S.C. § 112, second paragraph.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

Ssc:

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